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10/803,287

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Paul J. Hindrichs

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PATENT DOCKETING 39/361
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EXAMINER

IZQUIERDO, DAVID A

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,287

Applicant(s)

HINDRICHs ET AL.

Examiner

David A. Izquierdo

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3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 19,20,31,32,47-58 and 92-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,21-30,33-46,59-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-18, 21-30, 33-46, and 59-91 have been considered but are moot in view of the new ground(s) of rejection.
2. Applicant has argued that the combination of the helical anchoring structure of the Tremulis et al. reference ("Tremulis")(US 7,101,395) with the device and method of treating mitral valve insufficiency as taught by the Solem et al. reference ("Solem")(US 2001/0018611) is improper because the helical anchors of Tremulis would not function in combination with the Solem device. However, Should the anchors of Tremulis be placed remote to the device and attached to the device via sutures, as show in Figure 75 of Tremulis, the combination would yield a usable device with predictable results.
3. Furthermore, Applicant has argued that the catheter-based technology of the Solem reference fails to disclose specific features of independent claims 76, 79, 81, 85, and 89. Specifically, Applicant has argued that the prior art fails to disclose an anchor structure disposed in the patient's right atrium and left ventricle. However, since these limitations occur in apparatus claims and constitute functional language the prior art only needs to be capable of being disposed within the right atrium and left ventricle. Since the Solem reference pertains to instrumentation for use within the anatomy of the heart it is certainly capable of being placed within the left ventricle or right atrium.
4. Applicant has further argued that Solem fails to provide delivery instrumentation which contains a lateral curvature however, the delivery instrumentation, being a catheter-based system

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(Para. 0070) would inherently have such a curvature in order to avoid damage to the surrounding tissue.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5, 8-18, 21-30, 33-40, 44-46, and 59-64, and 68-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tremulis et al ("Tremulis") (US 2004/0049211) in view of Solem et al. ("Solem") (US 2001/0018611).

7. Solem discloses a method and device for treatment of mitral insufficiency comprising a first anchor structure (30), a second anchor structure (31), and linking structures (32, 33, 34) wherein the linking structures shortens the distance between the first and second anchor (paragraph 61) by means of flexible members (35) attached thereto. Solem further discloses use of a catheter for percutaneous implantation of the device through the coronary sinus wherein the device maybe manipulated in situ (paragraph 0024-0026).

8. However Solem fails to disclose helical anchors which penetrate the surrounding tissue. Tremulis discloses helical anchors which penetrate tissue by means of a sharpened wire torqueing through tissue (col. 15, lines 55-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to use helical anchors as taught by Tremulis with the device to treat mitral valve insufficiency, as per Solem the rationale being that the helical anchors of Tremulis are a well known technique by which to secure a device to the surrounding

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tissue and such a device would provide predictable results because such a combination is disclosed within Tremulis at Figure 75. (NOTE: The elected species receives filing date of the second provisional application filed 11/10/03 because the elected species was not disclosed in the prior provisional application).

9. Claims 6, 7, 41-43 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem in view of Tremulis in further view of Alferness et al. ("Alferness") (U.S. Patent Number 6,908,478). Solem in view of Tremulis discloses a method and device for treatment of mitral insufficiency as disclosed above however Solem in view of Tremulis fails to disclose a ratcheting structure between the anchors. Alferness discloses a ratcheting structure which cinches two anchors together. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the ratcheting linkage of Alferness to the device to treat mitral valve insufficiency, as per Solem in view of Tremulis the motivation to combine being that the ratcheting structure would allow greater control of the tension between the devices (Alferness: Col. 5, line 55-67 and Col. 6, lines 1-9).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Izquierdo whose telephone number is 571-272-1943.

The examiner can normally be reached on Monday through Friday from 8:00 am until 4:30 pm.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Izquierdo



Patent Examiner



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